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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,803	04/09/2002	Thomas Kissel	99/074 MED	5609
38263	7590	02/24/2006	EXAMINER	
PROPAT, L.L.C. 425-C SOUTH SHARON AMITY ROAD CHARLOTTE, NC 28211-2841			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,803	KISSEL ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7, 9 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8, 10-13, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/030,803.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/11/02, 4/9/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 10/26/05 and the response to the notice of non-compliant amendment filed 11/29/05. The amendment and the remarks filed with the response to the notice of non-compliant amendment are acknowledged.

Claims 1-16, 18 and 19 are pending.

Priority

The claim of DE 199 33 024 7 filed 07/04/2000 as a foreign priority document is acknowledged. However, a certified copy is not in the electronic file wrapper.

Election/Restrictions

Applicants were required to elect formula I or II for the purposes of examination; applicants were further requested to elect a specific formula I or II that is completely defined by single A, B, X or b or D or Y and n. However applicants provisionally elected a “compound formed solely of A, B and X and n, processes to form the same, and complexation of the same with DNA,” which applicants state are claims 17, 8 and 18 “respectively” However, no specific A and X and n were elected. The election was made with extreme traverse on the basis that the compounds are obtained by the same process. This is not found persuasive because the process for making the compound may be different from what is claimed and the compound can be used in materially deferent process.

The requirement is still deemed proper and is therefore made FINAL.

Claim 17 is cancelled. The compound A-(X-B)_n is present in claims 1-4, 6, 8, 10-13, 18 and 19. The elected species read on claims 1-4, 6, 8, 10-13, 18 and 19. Claims 5, 7, 9, 14-16 are withdrawn from consideration as containing non-elected subject matter.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6, 8 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokomichi et al. (US 5,204,196 cited by applicants on form PTO-1449).

Yokomichi discloses PEG-X-PEI block copolymer (abstract; column 1, lines 34-46); PEG is the hydrophilic moiety having an average molecular weight of 550 and polyethyleneimine having average molecular weight of about 1300 (Example 1). The molecular weight of both the PEG or PEO and PEI meet the limitations of the recited molecular weight.

3. Claims 1-4, 6, 8, 10-13, 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/59064, cited by applicants on form PTO-1449 and the specification).

WO 98/59064 discloses DNA complexes with PEG-PEI conjugate copolymer (English abstract; Examples 1-3), methoxy-succinimidyl propionate PEG (M-SPA-PEG) reacts with the imine (Example 2); the molecular weights of the PEG and PEI meet the limitations of the recited molecular weight (Example 2). The DNA is contacted with the complex of PEG and PEI (Examples 1 and 2). The WO publication meets the limits of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10-13 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokomichi et al. (US 5,204,196 cited by applicants on form PTO-1449) in view of Ogris et al. ("PEGylated DNA/transferrin-PEI-complexes: reduced interaction with blood components, extended circulation in blood and potential for systemic gene delivery" in **Gene Therapy** Volume 6, Issue 4 , April 1999, Pages 595-605).

Yokomichi is discussed above. Yokomichi discloses the copolymer of PEG and PEI. Yokomichi does not disclose a complex of DNA with the copolymer. However, Ogris discloses that the complexes can be formed between DNA and PEI and PEG and the complex is formed by contacting the DNA with PEI and PEG (abstract). According to Ogris, pegylation of the complexes reduces plasma protein binding and erythrocyte aggregation, the pegylated complex mediated reporter gene transfer to tumor without significant toxicity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare pegylated DNA complex with PEI with the expectation that therapy with the pegylated DNA complex would reduce toxicity while reducing protein binding and erythrocyte aggregation.

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Observation:

Claim 16 depends on claim 7 and recites that compound of formula I or II comprises nucleic acid. This requirement appears to be improper because claim 7 is directed only to compound of formula I. Thus, claim 16 is not considered with the examined claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

